SUMMARY OF PRODUCT CHARACTERISTICS.

1. **Name of the medicinal product**
   Dacof Mucolytic Syrup.
2. **Qualitative and quantitative composition**
   Each 5ml contains: Salbutamol (as sulphate) BP 2.0mg, Guaifenesin BP 100.0mg and Bromhexine HCl BP 4.0mg.

3.0 Pharmaceutical form: Syrup for oral administration.

4.0 Clinical particulars

4.1 Therapeutic indications

For productive coughs associated with acute and chronic bronchitis, common cold, bronchial asthma and other bronchospatic disorders.

4.2 Posology and method of administration:

Dosage: Dacof Mucolytic Syrup is administered orally by mouth.

To be taken three to four times a day. *Adults and children over 12 years*: two 5ml spoonfuls or as directed by the physician.

Children: 6-12 years: One 5 ml spoonful or as directed by the physician. *2-5 years*: As directed by the physician.

4.3 Contraindications

Dacof mucolytic is contraindicated for use in-patients with known hypersensitivity to any of the components of the preparation.

4.4 Special warnings and precautions for use

Dacof Mucolytic is to be administered with caution in patients with cardiovascular disorders like ischemic heart disease, hypertension and cardiac arrhythmias; hyperthyroidism, diabetes, those who are unusually responsive to sympathomimetics or who have convulsive disorders. Dacof mucolytic should be administered during pregnancy and lactation only if strictly required. Bromhexine (in Dacof) is required to be administered with caution in those with peptic ulceration, severe hepatic and renal dysfunction. Menthol containing products (Dacof) should be avoided in those with hiatal hernia, gallstones and in near-term pregnant females.

4.5 Interaction with other medicinal products and other forms of interaction

Salbutamol (in Dacof) can cause deleterious cardiovascular side effects when combined with sympathomimetics. Beta blockers cannot be used together since they block salbutamol action. Salbutamol (in Dacof) can increase the action of monoamine oxidase .inhibitors (MAOIs), nonpotassium-sparing diuretics, digoxin, tricyclic antidepressants to cause untoward reactions.

4.6. **Pregnancy and lactation**

Dacof mucolytic syrup is excreted in breast milk .Therefore it is not recommended for breastfeeding mothers unless the potential benefits to the patient are weighed against the possible risk to the infant.

4.7 Effects on ability to drive and use machines

No effect on driving and use of machines.

4.8 Undesirable effects

Its common side effects include muscle cramps, tachycardia, palpitation, fine muscle tremor, headache, peripheral vasodilation, restlessness, allergic reactions, fatigue, insomnia, dizziness, heart bum and GI bleeding over long time use.

4.9 Overdose.

Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and should be treated symptomatically.

5. 0 Pharmacological properties

5.1 Pharmacodynamic properties.

Pharmacotherapeutic group: Mucolytic, **ATC code**: R05CB03**.**

Pharmacology:

Salbutamol is a direct-acting sympathomimetic with mainly beta-adrenergic activity and a selective action on beta2 receptors. This results in its bronchodilating action being more prominent than its effect on the heart.

Salbutamol is used as bronchodilators in the management of reversible airways obstruction Bromhexine is a mucolytic used in the treatment of respiratory disorders associated with productive cough. Guaifenesin is reported to increase the volume and reduce the viscosity of tenacious sputum and is used as an expectorant for productive cough , Menthol is used as a hydrating agent to liquefy mucus and also have a demulcent effect. It has also been suggested that the apparent benefits of menthol in nasal congestion may be due to an effect on calcium channels of sensory nerves.

5.2 Pharmacokinetic properties

Salbutamol is readily absorbed from the gastrointestinal tract. It is subject to first-pass metabolism in the liver and possibly in the gut wall; the main metabolite is an inactive sulfate conjugate. Salbutamol is rapidly excreted in the urine as metabolites and unchanged drug; there is some excretion in the faeces. Salbutamol does not appear to be metabolised in the lung, therefore its ultimate metabolism and excretion after inhalation depends upon the delivery method used, which determines the proportion of inhaled salbutamol relative to the proportion inadvertently swallowed. The plasma half-life of salbutamol has been estimated to range from 4 to 6 hours.

Bromhexine hydrochloride is rapidly absorbed from the gastrointestinal tract and undergoes extensive first-pass metabolism in the liver: its oral bioavailability is stated to be only about 20%. It is widely distributed to body tissues. About 85 to 90% of a dose is excreted in the urine mainly as metabolites. Bromhexine is highly bound to plasma proteins. It has a terminal elimination half-life of up to about 12 hours. Bromhexine crosses the blood-brain barrier and small amounts cross the placenta. Administration of bromhexine hydrochloride by mouth to healthy subjects produced peak plasma concentrations after about 1 hour.1 Only small amounts were excreted unchanged in the urine with a half-life of about 6.5 hours. Guaifenesin is absorbed from the gastrointestinal tract. It is metabolised and then excreted in the urine. After absorption, menthol is excreted in the urine and bile as a glucuronide

5.3 Preclinical safety data

No additional data of relevance.

6. Pharmaceutical particulars

6.1 List of excipients

Menthol crystals,
Neutral spirit,
Sodium benzoate,
Sodium saccharin,
Sodium methyl paraben,
Sodium propyl paraben,
Bronopol, glycerin,
Sugar,
Propylene glycol,
Citric acid,
Tartrazine colour,
Raspberry flavour liquid
Purified water.

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months from the date of manufacture. (3 years).

6.4 Special precautions for storage

Store in a dry place, below 30°C. Protect from light.

6.5 Nature and contents of container

100 mL pack in PET bottle in a unit box along with a literature insert.

6.6 Special precautions for disposal and other handling

None applicable.

7. **Marketing authorization holder/Registrant**.

Dawa limited
Plot No.7879/8, Baba Dogo Road, Ruaraka,
P.O Box 16633-00620, Nairobi –Kenya

8. **Manufacturer**

Dawa Limited
Plot No.7879/8, Baba Dogo Road, Ruaraka
P.O.BOX 16633-00620
Nairobi, Kenya.
Email:admin@dawalimited.com

9. Date of revision of the text:

June 2019.